DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

August 20, 1999

VIA FACSIMILE
CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Marc S. Isaacs, President
Sun Orchard Inc.
1198 W. Fairmont Drive
Tempe, AZ 85282

W/L 43-9

Dear Mr. Isaacs:

During an inspection of your orange juice manufacturing facility located at 1198 W. Fairmont Drive, Tempe, Arizona conducted June 24 to July 6, 1999, we found that you caused to be manufactured and distributed unpasteurized (i.e., not heat treated) orange juice products under the following labels:

"SUN ORCHARD 100% FRESHLY SQUEEZED ORANGE JUICE"
"VIOLA FRESHLY SQUEEZED ORANGE JUICE...100% JUICE FROM THE FRUIT"
"VIOLA JUICES FRESHLY SQUEEZED ORANGE JUICE PURE JUICE"
"earl's and joey tomato's 100% PURE JUICE FRESH ORANGE JUICE"
"Aloha Juice Co.100% Freshly Squeezed Orange Juice"
"MARKON FIRST CROP. Freshly Squeezed ORANGE JUICE"
"TRADER JOE'S 100% FRESH JUICE Orange Juice"
"SYSCO NATURAL Natural Freshly Squeezed Orange Juice"
"BARREL OJ 52 GAL. SUN ORCHARD INC."
"BUCKETS 4.5 GAL. PROD. ORANGE JUICE SUN ORCHARD INC."
"CONDENSED MARGARITA MIX SUN ORCHARD INC."
"VAREVA OJ 61.5 OZ FROZEN"

Our investigation revealed that your Tempe, Arizona facility manufactured and distributed unpasteurized orange juice between June 9 and June 25, 1999 that was adulterated under section 402(a)(1) of the Act because the juice was contaminated with the pathogenic bacteria *Salmonella* which may render the juice injurious to health. Health officials linked consumption of your unpasteurized orange juice to an outbreak of *Salmonella* serotype Muenchen within the United States and Canada. When notified, you conducted a voluntary recall of the adulterated product from the marketplace and ceased

manufacture and distribution of unpasteurized orange juice to prevent further illnesses. We acknowledge your action in this regard.

Our investigation revealed *Salmonella* contamination as follows:

- Unpasteurized orange juice under any label with lot numbers 9160, 9163, 9164, 9166, 9172 and 9175 contained an added poisonous or deleterious substance (*Salmonella spp.*) making the juice unsafe to consume.

    1. We isolated *Salmonella* serotype Muenchen from finished retail units of lot numbers 9160 and 9164.

    2. We isolated *Salmonella* serotypes Muenchen, Hildago, Montevideo, Gaminara, Javiana and an untypable serogroup N from retain samples for finished product lot numbers 9160, 9163, 9166, 9172 and 9175.

Furthermore, we isolated *Salmonella* from each of [redacted] juice holding tanks within your Tempe, Arizona facility. You used these holding tanks to blend juice during manufacture of unpasteurized orange juice. The presence of *Salmonella* in the [redacted] gallon holding tank that we sampled on June 25, 1999, and which you cleaned only a short time earlier on June 22, 1999, raises concern about the efficacy of your cleaning and sanitizing procedures. Gross contamination with several different *Salmonella* serotypes is extremely unusual and in our opinion suggests a serious breakdown in control over either your suppliers or transportation, or both.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Moreover, it is your responsibility to produce safe products. You should take prompt action to prevent further violation of the Act. Further violation of the Act may result in regulatory action without further notice, which can include seizure of your products and/or injunction of your firm.

We are concerned about information gathered during our investigation involving the transportation of the juice from [redacted] to your Tempe, Arizona facility. Our investigation revealed that ice was added, in what appears to have been a routine practice, to bulk tanker trucks transporting unpasteurized orange juice into the United States. Not only may this practice have contributed to *Salmonella* contamination, but orange juice as described in Title 21, Code of Federal Regulations (CFR) 146.135(a) is the unfermented juice obtained from certain species of mature *Citrus* oranges. Water (frozen or liquid) cannot be added to orange juice without compromising this orange juice standard of identity. This constitutes adulteration of the orange juice under section 402(b) of the Act and would result in misbranding of the finished product under section 403(g) of the Act.

Your letter dated August 13, 1999, acknowledges the addition of ice and its possibility for providing an avenue for contamination with harmful bacteria. Although we acknowledge that you terminated business with the implicated supplier [redacted] we are concerned that your firm may have had knowledge of earlier imported unpasteurized orange juice shipments that contained ice. We are particularly concerned about this since the imported unpasteurized orange juice was destined for packaging and distribution as unpasteurized orange juice and that the juice would not be subject to any further treatment capable of removing or destroying organisms of public health significance.

Your letter dated August 13, 1999, informed us of the steps that you are taking to prevent your unpasteurized orange juice from being unsafe. You also advised that you intend to resume unpasteurized orange juice production on Monday, August 23, 1999. For your information, FDA intends to discuss recent developments concerning production of unpasteurized juice and application of the 5-log reduction process with the industry. This meeting will be held in Washington, D.C. next week and we will be extending an invitation to you to attend. We request that you withhold production of unpasteurized orange juice without the warning statement until after this meeting.

Please notify this office in writing within 15 working days of receipt of this letter of the specific actions taken to correct the noted violations and prevent their recurrence. If corrective actions can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your written response should be directed to the attention of:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,

James E. Kozick

James E. Kozick
Acting District Director